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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	15

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,524	HOFMANN, THOMAS	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,28-33,35 and 37* is/are pending in the application.

4a) Of the above claim(s) *27,34 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26, 28-33, 35, 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Request Continued Examination, Extension of Time, and Amendment C received June 25, 2003 and Supplementary Information Disclosure received on August 15, 2003 is acknowledged. Claims 1-26, 28-33, 35, 37 are pending in this application. Claims 27, 34, and 36 are withdrawn form prosecution.

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species 1: spray vial, spray pump, atomizer, nebulizer, aerosolizer, and dry powder inhaler.

Species 2, humidifier

Species 3: mask

Species 4: nasal drops

Species 5: lozenges

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Hana Verny on September 10, 2003 a provisional election was made with traverse to prosecute species 1. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27, 34, and 36 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The amendment filed June 25, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The applicant has amended the specification to read sodium bicarbonate. However, applicant's original specification reads sodium hydrogen; thus applicant does not have support for this amendment.

Applicant is required to cancel the new matter unless support can be provided, in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26, 28-33, 35, 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating snoring, sleep apnea or sudden infant death syndrome, does not reasonably provide enablement for preventing snoring, sleep apnea or sudden infant death syndrome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, and the working examples. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention: The claim is drawn to a method of treating or preventing snoring, sleep apnea or sudden infant death syndrome. The nature of the invention is complex in that it encompasses the prevention of snoring or sleep apnea with the instant compound such that an individual never has the instant respiratory disorder.

Breadth of Claims: The complex nature of the claim is greatly exacerbated by the breadth of the claim. The claim encompasses the prevention of snoring, sleep apnea, and SIDS and the actual cause of the disorders are due to several factors, i.e.

age, sex, obesity, upper airway structural abnormalities, etc. This may or may not be addressed by the administration of the composition.

State of the Art: While the state of the art recognizes alleviation of the disorders with the use of synthetic surfactants, the connection between the actual cause of the disorder and the prevention of the disorder itself has not been established. The state of the art recognizes the treatment of the symptoms of the disorder may be through the administration of alkylaryl polyether alcohol. For instance, the actual cause of SIDS in the art is not known, many possible theories exist in the art.

Guidance of the Specification: The guidance given by the specification as to how one would administer the claimed composition in order to actually prevent the disease is minimal. All the guidance provided by the specification is directed towards the treatment rather than the prevention of snoring, sleep apnea, and SIDS. For instance, the actual prevention of snoring is not demonstrated, rather the treatment is with continued administration of the instant compound, snoring is treated. However, the actual cause and cure of the snoring is not addressed.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual prevention of the disorders in a human subject with the administration of the instant composition makes practicing the claimed invention unpredictable in terms of the prevention of the disorder.

Working Examples: All the working examples provided by the specification are directed toward the treatment rather than the prevention of the disorder.

For the stated reasons above, the rejection based on enablement is deemed proper.

Claim Objections

Claim 37 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 37 depends from independent claim 30, which recites consisting claim language. Therefore, the use of instant claim language closes the claims to recited ingredients, i.e. alkylaryl polyether alcohol and pharmaceutically acceptable excipients, additive, or diluents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-12, 14-15, 17-18, 21-23, 25-26, 30-33, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy et al (5,849,263).

Kennedy et al disclose a pharmaceutical composition containing 0.25%-5% tyloxapol and a carrier medium (distilled water/saline) for the treatment of respiratory diseases and distress. See column 7, lines 43-45 and column 11, lines 19-21. Kennedy discloses the Alevaire formulation containing 0.125% tyloxapol, 2% $NaHCO_3$, and 5% glycerol. See example 6. For administration of nasal airway for relief of nasal rhinitis or

rhinosinusitis, the tyloxapol is administered in the form of a fine spray from a squeeze bottle. See column 12, lines 1-10. Kennedy discloses a jet aerosol nebulizer system. See column 11, lines. Kennedy discloses an anti-inflammatory drug included in the formulation. See column 11, lines 30-52. The reference discloses a tyloxapol formulation for asthma. See column 19, lines 25-30.

Note that the intended use of a composition or device does not hold patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 19-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al (5,849,263).

Kennedy et al disclose a pharmaceutical composition containing 0.25%-5% tyloxapol and a carrier medium (distilled water/saline) for the treatment of respiratory

diseases and distress. See column 7, lines 43-45 and column 11, lines 19-21. Kennedy discloses the Alevaire formulation containing 0.125% tyloxapol, 2% $NaHCO_3$, and 5% glycerol. See example 6. The reference teaches the composition for asthma. See column 19, lines 25-30.

Kennedy et al do not specify the instant amount. Kennedy does not specify the type of physical activity.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the concentration of the prior art's formulation through routine experimentation. Differences in concentrations do not impart patentability for subject matter encompassed by the prior art unless an indication of criticality is shown. One would be motivated to do so since Kennedy provides the general parameters of the formulation and manipulation is based on the desired pH, isotocity, etc.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to treat nasal breathing due to physical activity. One would be motivated to do so since Kennedy teaches the treatment of nasal breathing, i.e. asthma or rhinitis. Therefore, one would expect similar results in improving breathing due to another cause. The source per se of problems with nasal breathing does not impart patentable distinction unless it imputes a different characteristic from that known in the art.

Claims 13 and 16, 28-29, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al (5,849,263) by itself or in view of Meyer et al (5,958,902).

Kennedy et al disclose a pharmaceutical composition containing 0.25%-5% tyloxapol and a carrier medium (distilled water/saline) for the treatment of respiratory diseases and distress. See column 7, lines 43-45 and column 11, lines 19-21. Kennedy discloses the Alevaire formulation containing 0.125% tyloxapol, 2% NaHCO3, and 5% glycerol. See example 6. Kennedy teaches the utilization of EXOSURF for neonatal RDS and the dosage. Kennedy discloses that the application of EXOSRUF, which contains other ingredients besides tyloxapol, was noted with side effects. See column 6, lines 3-41. Kennedy teaches the utilization of the tyloxapol alone for conventional applications in the art but without the side effects of the other ingredients such as DPPC. Kennedy teaches the without the use of hypertonic agents or other active ingredients (DPPC), one can derive higher concentration of tyloxapol for less and frequent and more rapid administration. Further this increases tyloxapol's benefits such as its reduced toxicity and enhanced half-life, while avoiding the side effects associated with other ingredients. See column 8, lines 29-42.

Kennedy does not specify all the instant respiratory diseases.

Meyer teaches the application of a lung surfactant to the reduce sleep apnea. The lung surfactant is EXOSURF. See column 4, lines 50-54. Meyer teaches the use of several devices to deliver nasal compositions with instant attachments. For instance a tapered extension nozzle for direct application to the pharyngeal region. See column 5, lines 42-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kennedy et al and Meyer et al and

utilize Kennedy's composition to treat sleep apnea and SIDS. One would be motivated to do so since Meyer teaches EXOSURF to treat sleep apnea and since SIDS is the cessation of respiration while an infant sleeps, one would expect that a composition that treats apnea will treat SIDS because SIDS falls into the category of sleep apnea. Furthermore, Kennedy teaches the conventional use of EXOSURF for neonatal RDS and SIDS is a form of neonatal respiratory distress. Lastly, one would have expectation of similar results with the interchangeable use of EXOSURF and Kennedy's tyloxapol formulation since Kennedy teaches that the composition containing tyloxapol only can be applied in the same manner as the prior art formulation (EXOSURF) without the side effects. Therefore, Kennedy teaches the application of his formulation for all prior applications of EXOSURF.

Lastly, it is deemed obvious to one of ordinary skill in the art to use the appropriate dosage form and device to administer the composition. One would be motivated to do so based on the area to be treated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

MICHAEL G. HARTLEY
PRIMARY EXAMINER